

Remarks:

Reconsideration of the application is requested. Claims 1-7, 16-19, 24, 26-57 are now in the application. Claims 1, 4, 16-19, 26, 44-46 have been amended. Claims 51-57 have been added.

Support for amendments to claims 1 and 26 can be found in paragraphs [0014] and [0063].

Claim Objection:

In the third paragraph of page 2 of the Office action, the Examiner objected to claims 1 and 40 as containing typographical errors. While the Applicant believes that the claims were clear as previously presented, the Applicants believe that the suggested changes do not affect the scope of the invention. And, in light of the Examiner's recommendation, Applicant has entered the suggested change.

The insertion of the words --one of-- and the replacement of "surface" with --surfaces-- is not done for reasons related to the statutory requirements of a patent or for reasons related to the prior art.

35 USC 112

In the final paragraph on page 2 of the Office action, the Examiner rejected claims 4, 6, 24, and 44-46 as being indefinite under 35 U.S.C. § 112, second paragraph. More specifically, the Examiner has stated that the claims combined method steps in a device claim.

Claim 4 has been amended to change "is varied" to --is variable--.

Claims 6 and 24 have not been amended. The language in claims 6 and 24 (i.e. "is positioned") describes a spatial relationship of parts relative to each other within the device. The language does not describe the act of positioning. Accordingly, claims 6 and 24 do not in fact describe a method step. Accordingly, the claims are definite as written. If the Examiner is still concerned, he is asked to telephone the undersigned attorney so that different language can be proposed.

Claims 44-46 have been amended to change "is altered" to --is alterable--.

Accordingly, the claims meet the requirements of 35 U.S.C. § 112, second paragraphs. Should the Examiner find any further objectionable items, counsel would appreciate a telephone call during which the matter may be resolved. The changes are neither provided for overcoming the prior art nor do they narrow the scope of the claim for any reason related to the statutory requirements for a patent.

35 USC 101

The Examiner rejected claims 4, 6, 24, and 44-46 under 35 USC 101 as not belonging to one statutory class. As discussed with regard to the 35 USC § 112, second paragraph, rejections, the claims have been amended so that they only cover one statutory class: a machine.

35 USC 102

In the final paragraph on page three of the Office action, the Examiner rejected claims 26-29, 31, and 45 as being fully anticipated by Armao, US Patent No. 3,391,690 under 35 U.S.C. § 102(b). As will be explained below, the claims were patentable over the cited art in their original form and the claims have, therefore, not been amended to overcome the references.

Before discussing the prior art in detail, a brief review of the invention as claimed is provided. Claim 26 calls for a surgical instrument for delivery of an implant through tissue by magnetic attraction that includes:

a body;

a carrier located on the body for removably securing at least a portion of the implant to the instrument;

a tip located at a distal end of the body and configured and dimensioned for insertion through the tissue; and

a magnetic element located on the body, wherein interaction between the magnetic element and a magnetic field external to the tissue creates magnetic attraction to drive the implant through the tissue.

Paragraph [0048] of the specification describes that a “carrier” is a device for securing at least a portion of an implant (e.g. a suture) to the instrument. Paragraph [0048] further explains that a carrier can be embodied as a slot, eyelet, or barb. *See especially* new claims 51-53.

Armao ‘690 does not disclose a carrier. Nothing in Armao ‘690 teaches a carrier for removably securing at least a portion of the implant to the instrument. Armao ‘690 does not teach attaching any implant to the instrument. Armao ‘690 does not teach any implant. Armao ‘690 teaches a device for scooping a biopsy. If an implant were placed in the jaws of Armao ‘690, the jaws would cut the implant.

With regard to claim 29, although it does not affect the rejection, Applicant notes that “permanent magnet” is a term of art. Permanent magnet does not mean one that is not removed. According to Miriam-Webster, a permanent magnet is “a magnet that retains its magnetism after removal of the magnetizing force.” A permanent magnet contrasts, for example, an electromagnet that loses its magnetizing force after the electric current is cut.

Because Armao ‘690 does not teach a body with a carrier (especially, a slot, eyelet, or barb) for removably securing at least a portion of the implant to the instrument, Armao ‘690 does not anticipate claims 26-29, 31, 45, and 51-53 of the instant application.

35 USC § 103

In the final paragraph on page 4 of the Office action, the Examiner rejected claim 30 as being unpatentable over Armao ‘690 under 35 USC § 103(a). The Examiner stated, “Armao discloses the claimed invention except for an electromagnet magnetic element. However, the applicant has failed to disclose that such a magnet provides an advantage.”

In contrast to the Examiner’s assertion, paragraph [0048] of the specification explains, “Magnetic field generator 66 is an electromagnet and is provided with a controller for electronically varying the generated electric field.” The magnetic field generator contrasts a permanent magnet that must be moved to vary the field on the magnetic element. So, the advantage of an electromagnetic magnet element is that the field strength can be changed without

changing the relative position. This advantage over a permanent magnet is not taught or suggest by Armao '690. Accordingly, Armao '690 does not form a *prima facie* case of obviousness as is required under 35 USC § 103(a).

In the first full paragraph on page 5 of the Office action, the Examiner rejected claims 1-7, 19, 24, 32-44, and 46-50 as being unpatentable over Armao '690 in view of Francischelli US Patent No. 6,699,240 under 35 USC § 103(a).

Claim 1 has been amended to distinguish the invention from the prior art. Support for the change to claim 1 can be found in paragraph [0014] of the specification. Amended claim 1 describes an apparatus for moving a medical implement through tissue. The apparatus includes the following features:

a first tissue engaging surface being configured to releasably hold the medical implement and to contact a first tissue section;

a second tissue engaging surface being movable relative to said first tissue engaging surface in order to contact a second tissue section and to penetrate the medical implement into the tissue;

a magnetizable material being disposed in one of said first and second tissue engaging surfaces; and

a magnetic field generator disposed in one of said tissue engaging surfaces not containing said magnetizable material and generating a magnetic field to move said magnetizable material relative to said magnetic field generator, thereby driving the medical implement through the first tissue section and through the second tissue section at some moment by magnetic attraction alone. (Emphasis added by Applicant.)

Neither Armao '690 nor Francischelli '240 teach a surface configured to releasably hold the medical implement that is being passed through the tissue.

Armao '690 is a device (i.e. a scoop) for collecting a biopsy. No implement (e.g. needle, suture, or suture anchor) is being passed through tissue by the Armao '690 device. Likewise, Francischelli '240 teaches a device for ablating tissue. The electromagnetic-powered sheers do not release an implant to be passed through the tissue. Accordingly, Armao '690 in view of

Francischelli '240 do not form a *prima facie* case of obviousness as is required by 35 USC § 103(a). Therefore, claim 1 is patentable.

If the Examiner still believes that the claim does not recite enough structure, new claim 55 positively claims a holder on the first surface for releasably holding the implement. Support for new claim 55 is provided in paragraph [0066] of the specification.

New claim 54 further emphasizes that there is a medical implement that is releasable from one surface and that is to be moved to the second surface. No such implant is taught or suggested by the references.

Claim 32 is patentable for the additional reason that prior art does not suggest to one with ordinary skill in the art to spread tissue. Applicant acknowledges that the Armao '690 and Francischelli '240 devices could be used to spread tissue. However, this is not the issue in a 103 analysis. The issue is whether one with ordinary skill in the art would be suggested to make the invention as claimed. One with ordinary skill in the art would have no suggestion of using the devices for spreading tissue. Armao '690 teaches to punch a biopsy. Francischelli '240 teaches ablation shears. Nothing in these references suggests to spread tissue. Accordingly, the invention described in claim 32 is not obvious.

Claims 40, 56, and 57 are patentable for the same reasons discussed previously with regard to claims 1, 54, and 55, respectively.

Claim 41 is patentable over the prior art for the same reasons that were discussed previously in this response with regard to claim 32.

The remainder of the rejected claims are patentable for the same reasons as their underlying base claims.

Rejoinder

If claim 54 is allowable, then claims 16-18 should be rejoined.

Conclusion

In view of the foregoing, reconsideration and allowance of claims 1-7, 16-19, 24, 26-57 are solicited.

The Examiner is asked to carefully review the independent claims 1, 24, and 40. The changes to the claims do not necessarily require a further search. If the Examiner considers the independent claims allowable in light of the corrections and the remarks, then the Examiner should enter the amendment and allow the case even though the new dependent claims may have required a further search.

If a further extension of time for this paper is required, petition for extension is herewith made.

Petition for extension is herewith made. The extension fee for response within a period of one month pursuant to Section 1.136(a) in the amount of \$65 in accordance with Section 1.17 is enclosed herewith.

A Request for Continued Examination is attached herewith.

A payment of \$182 is attached to provide for seven additional total claims.

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No additional fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A04-002-1).

Respectfully submitted,

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